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December 18, 2006

VIA FACSIMILE
EXPEDITED PROCEDURE

To: Examiner Carolyn Smith
Group Art Unit No. 1631
U. S. P. T. O.

Facsimile No. 571-273-8300

From: Phillip E. Miller

Facsimile No. 703-761-2375

Re: Filing of Reply Brief
U. S. Patent Application Serial No. 09/870,009
Our Ref: YOR.418

Dear Examiner:

Enclosed please find an Reply Brief filed in response to the Examiner's Answer dated October 18, 2006.

Thank you in advance for your kind consideration of this case.

Very truly yours,

Phillip E. Miller

PEM/ess
Enclosure

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09/870,009
JP920000069US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Kashima et al.

Serial No.:	09/870,009	Group Art Unit:	1631
Filed:	May 30, 2001	Examiner:	Carolyn L. Smith

For: NUCLEOTIDE SEQUENCE FOR IDENTIFYING A SOURCE OF GENETIC INFORMATION, AND DNA AND CELL INCLUDING THE SAME

Honorable Commissioner of Patents
Alexandria, VA 22313-1450

APPELLANT'S REPLY BRIEF

Sir:

Comes now the Appellant and in response to the Examiner's Answer dated October 18, 2006, states as follows:

I. The New Ground of Rejection

In addition to the rejections included in the Office Action dated January 24, 2006, the Examiner now alleges that claims 5, 8-12, 15, 17-27 and 30-34 are not patentable under 35 USC 101 as allegedly encompassing "viral genomes comprising LTRs (long terminal repeats)".

However, as Appellant has **repeatedly** pointed out to the Examiner, the claimed invention (e.g., of claim 5) is directed to DNA which includes a nucleotide sequence which is 1) is **not naturally occurring** in the DNA and 2) is **embedded** in a portion of the DNA which is other than a gene portion, and 3) **includes source identification information which identifies a source of a predetermined gene** in the gene portion.

For example, assume that ACME Corporation bioengineers a new gene which may improve the speed or endurance of a racehorse. ACME Corp. may embed that gene (a "value-added" gene) in the DNA of a racehorse, so that the offspring of that racehorse may include that gene. Of course, ACME Corp. could make a fortune by marketing these racehorses that

have this gene and, therefore, ACME Corp. will likely want to prevent others from copying the gene.

However, identifying copies of this gene may be difficult conventionally because it is hard to distinguish copying from gene mutation (Application at page 3, lines 8-12). That is, just because a racehorse has the gene does not mean that the bioengineered gene from ACME was copied, since the gene may have occurred in that racehorse by a genetic mutation.

However, using the claimed invention, ACME Corp. could **also embed** in the racehorse's DNA, **a nucleotide sequence (e.g., a watermark sequence) identifying ACME Corp. as the source of the gene.** Whenever ACME's gene is copied, this watermark sequence (identifying ACME as the source of the gene) may be copied as well. Thus, if the gene occurs in a racehorse, it may be easy to determine whether it occurred by copying the gene bioengineered by ACME Corp. **by determining whether the watermark sequence also occurs in the racehorse's DNA.** That is, if the watermark is present in the DNA, the gene was likely copied, but if no watermark is present in the DNA the gene may have occurred by genetic mutation (Application at page 13-20).

The Examiner surprisingly alleges that "the DNA and cells recited in the instant claims are not limited to be different from those existing in nature". However, in the claimed invention, the nucleotide sequence added to a portion of DNA is not just any old nucleotide sequence, but instead is a nucleotide sequence that is "not naturally occurring".

Morcover, the nucleotide sequence includes 'source identification information" which identifies a source of the genetic information in the gene portion. Appellant submits that this certainly implies some human intervention. That is, without human intervention the 'source" of any genetic information in a gene portion is not an issue.

Further, the source identification information "identifies" a source of the genetic information in the gene portion. Appellant again submits that this implies some human intervention. That is, the source identification information is not likely intended for identifying genetic information without at least some human intervention. Indeed, common sense again dictates that some human intervention is required for identifying the source of the genetic information.

Further, claim 5 defines DNA having a nucleotide sequence which is "embedded in" a

portion of the DNA. Appellant again submits that common sense dictates that human intervention is required to **embed** the nucleotide sequence to a portion of DNA. Therefore, the claimed DNA in which a nucleotide sequence has been embedded inherently requires human intervention and is by definition not naturally-occurring.

Further, Appellant would point out that 35 USC 101 states that whoever invents "any new or useful ... composition of matter ... may be patented". Appellant would again point out that the claimed invention (e.g., of claim 5) is directed to not simply "DNA", but DNA which includes a nucleotide sequence that 1) is **not naturally occurring** in the DNA and 2) is **embedded** in a portion of the DNA which is other than a gene portion, and 3) **includes source identification information which identifies a source of a predetermined gene** in the gene portion. Thus, the DNA would clearly be considered a "composition of matter" under 35 USC 101 and therefore patentable subject matter.

The Examiner is presumably alleging that the claimed invention would fall under the "natural phenomenon" judicial exception under 35 USC 101. However, the claimed invention is not a natural phenomenon like Newton's law of gravity or Einstein's $E=mc^2$. Instead, the claimed invention (e.g., as recited in claim 1) is directed to "DNA", and therefore, clearly does not fall under the "natural phenomenon" judicial exception under 35 USC 101.

Indeed, Appellant would also point out that the claimed invention is directed to DNA that includes not simply a "predetermined gene" (e.g., a value added gene"), but also includes the nucleotide sequence which is embedded in the DNA and identifies a source of the predetermined gene. That is, even assuming (arguendo) that the DNA would fall under some judicial exception under 35 USC 101, the DNA of the claimed invention may clearly be considered transformed "to a different state or thing" and produces a useful, concrete and tangible result, and is, therefore, patentable under 35 USC 101 (e.g., see *Diamond v. Diehr*, 450 U. S. 175 (1981)).

In view of the foregoing, the Board is respectfully requested to withdraw this rejection.

II. The Rejection of Claim 32 under 35 U.S.C. §112, First Paragraph

Appellant would again point out that, as noted in MPEP §2163, to satisfy the written description requirement, a patent specification need only describe the claimed invention in **sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention** (e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116). Further, Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Further, possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991)

In this case, it is completely unreasonable to suggest that the specification does not describe the claimed invention of claim 32 in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Indeed, Claim 32 recites "*wherein **said portion which is other than said gene portion** comprises a portion of said DNA which does not store a protein code sequence and transcription control information for said sequence*".

The Application states, for example:

> "*The form of the genetic information in a cell will now be described through an explanation of the overview of a process by which [a] gene codes for a protein molecule ... Arranged in the DNA are four bases. A (adenine), T*

(thymine), G (guanine) and C (cytosine). This sequence of the four bases (hereinafter the bases are referred to by their initials, A, T, G and C) of DNA consists of a gene portion wherein a protein code sequence and its transcription control information are stored, and a portion wherein genetic information is not included" (Application at page 12, line 24-page 13, line 6) (emphasis added).

That is, the Application defines a gene portion (e.g., in an exemplary aspect) as a portion where a protein code sequence and its transcription control information are stored. Thus, one of ordinary skill in the art would likely assume **and it is reasonable to conclude** that a portion other than a gene portion is a portion "*which does not store a protein code sequence and transcription control information for said sequence*", as recited in claim 32.

Thus, Appellant again respectfully submits that one of ordinary skill in the art would likely be able to read the specification and easily make and use the claimed invention of claim 32. Therefore, the Examiner has clearly failed to establish that claim 32 does not comply with the written description requirement under 35 U.S.C. §112, first paragraph.

Therefore, the Board is respectfully requested to withdraw this rejection.

III. The Rejection of Claims 8-10 under 35 U.S.C. §112, Second Paragraph

With respect to the phrase "intentionally designed", Appellant again notes MPEP 2173.02 provides that the Examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is **whether the claim meets the threshold requirements of clarity and precision**, not whether more suitable language or modes of expression are available. Further, MPEP 2173.02 provides that **some latitude in the manner of expression and the aptness of terms should be permitted** even though the claim language is not as precise as the Examiner might desire.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must **consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope** and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). Only if the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, is a rejection of the claim under 35 U.S.C. 112, second paragraph appropriate. See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993).

Appellant again submits that claim 8 clearly **meets the threshold requirements of clarity and precision**, especially if Appellant is given **some latitude in the manner of expression and the aptness of terms.**

Moreover, Appellant again submits that the term " **intentionally designed**" is used in claim 8 with "not naturally occurring" to distinguish the "at least one special sequence" from a naturally occurring sequence in DNA. Indeed, Appellant respectfully submits that one of ordinary skill in the art would likely consider the term "*not naturally occurring in said DNA and that is intentionally designed*" to mean a sequence which may be **intentionally designed by man**, as opposed to a naturally-occurring sequence in DNA (e.g., a sequence that is designed without any human intervention).

Further, the term is used to describe the "at least one special sequence" that includes "source identification information". In an exemplary aspect of the claimed invention, such a sequence may be referred to as a "watermark sequence". Such a sequence is clearly described in the Application, for example, at page 11, lines 2-21 and Figure 3.

Further, as with other "watermarks" (e.g., a digital watermark in software or an electronic document, etc.), in an exemplary aspect of the claimed invention, the "watermark sequence" may be embedded into DNA to help identify the source of a "value-added gene".

Therefore, Appellant again submits that when the definiteness of claim 8 is analyzed in light of the content of the Application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made, the term "intentionally designed" is clear and not indefinite".

Therefore, the Board is respectfully requested to withdraw this rejection.

IV. The Rejection of claims 5, 8-12, 15, 17-27 and 30-34 under 35 U.S.C. § 102(b) over Lizardi

Appellant again submits that contrary to the Examiner's allegations, Lizardi does not teach or suggest "*a nucleotide sequence which is not naturally occurring in said DNA and which is **embedded in said portion which is other than said gene portion**, and comprises source identification information **which identifies a source of said predetermined gene in said gene portion***", as recited in claims 5 and 12 and similarly recited in claims 8, 11, and 15.

Clearly, this feature not taught or suggested by Lizardi. Indeed, as noted above, the purpose of Lizardi is to provide an improved method for **detecting specific nucleic acids in a sample with high specificity and sensitivity**. Lizardi has nothing to do with identifying a source of genetic information (e.g., identifying a source of a value added gene).

Specifically, Lizardi teaches a method which includes 1) a DNA ligation operation, 2) an amplification operation, and 3) a detection operation. Lizardi states that the method has two features that "provide simple, quantitative, and consistent amplification and detection of a target nucleic acid sequence. First, target sequences are amplified via a small diagnostic probe .... . Second, amplification takes place not in cycles, but in a continuous, isothermal replication: rolling circle replication" (Lizardi at col. 2, lines 52-55; col. 3, lines 24-34)

Lizardi discloses at Figure 5, the open circle probe (OCP) which is a linear single-stranded DNA molecule containing preferably 70 to 100 nucleotides (Lizardi at col. 5, lines 22-25. The OCP includes portions such as the "detection tag portion".

The OCP is ligated and replicated to form a long DNA molecule (TS-DNA) containing multiple repeats of sequences complementary to the OCP which are called "target sequences" (Lizardi at col. 5, lines 55-67). Each end of the OCP includes a "target probe portion" which is 10 to 35 nucleotides and is complementary to a target nucleic acid sequence (Lizardi at col. 6, lines 12-24). For example, Figure 1 illustrates an OCP hybridized to a target sequence.

Lizardi teaches that in a ligation operation, an OCP hybridizes to its cognate target nucleic acid sequence (if present) followed by ligation of the ends of the hybridized OCP to form a covalently closed, single stranded OCP. After ligation, a rolling circle replication primer hybridizes to OCP molecules followed by rolling circle replication of the circular OCP molecules (Lizardi at col. 19, lines 32-41).

Lizardi teaches that multiplex rolling circle amplification (RCA) can be used to detect mutations in genes where numerous distinct mutations are associated with a certain disease (e.g., Huntington's chorea) (Lizardi at col. 22, lines 20-22). Lizardi teaches that the presence of one or more members of a group of target sequences may be detected by designing an OCP for each target sequence, where the target probe portions of each open circle probe are different but the sequence of the primer portions and the sequence of the detection tag portions of all the OCPs are the same. All of the OCPs are placed in the same OCP-target sample mixture and the same primer and detection probe are used to amplify and detect TS-DNA (Lizardi at col. 22, lines 28-40). If any of the target sequences are present in the target sample, the OCP for that target will be ligated into a circle and the circle will be amplified to form TS-DNA (Lizardi at col. 22, lines 40-42). Detection of TS-DNA resulting from ligation of any of the OCPs indicates that at least one member of the target sequence group is present in the target sample (Lizardi at col. 22, lines 46-48).

Thus, using the Lizardi method, OCPs may be mixed with a target sample to determine whether the target sample includes a target nucleotide sequence. This is completely unrelated to the claimed invention.

Therefore, Appellant again submits that Lizardi clearly does not teach or suggest each and every feature of the claimed invention. Therefore, the Board is respectfully requested to withdraw this rejection.

V. The Rejection of claims 5, 8-11, 15, 17-27, 30 and 34 under 35 U.S.C. § 102(b) over Arnot

Appellant again submits that contrary to the Examiner's allegations, Arnot does not teach or suggest "*a nucleotide sequence which is not naturally occurring in said DNA and which is **embedded in said portion which is other than said gene portion, and** comprises source identification information **which identifies a source of said predetermined** gene in said gene portion*", as recited in claims 5 and 12 and similarly recited in claims 8, 11, and 15.

Clearly, this feature not taught or suggested by Arnot. Indeed, the purpose of the Arnot method is to identify lineages of drug-resistant parasites, or to reconstruct local networks of parasitic infections (Arnot at page 23, col. 1). Certainly, Arnot has nothing to do with the claimed invention which includes DNA having a nucleotide sequence which is not naturally occurring in the DNA and which is embedded in a portion which is other than a gene portion, and includes source identification information which identifies a source of the predetermined gene.

Indeed, as noted above, the Examiner surprisingly attempts to equate the CS gene of Plasmodium falciparum with a "predetermined gene" in the claimed invention, the CS repeats with the "gene portion" of DNA in the claimed invention, the "flanking region" in Arnot with the "portion which is other than said gene portion" in the claimed invention, and the CS region flanking primer with the "nucleotide sequence which is not naturally occurring in said DNA" of the claimed invention. The Examiner further alleges that the flanking primer identifies a source of a predetermined gene.

The Examiner's allegations are surprising and completely unreasonable.

Appellant would again point out that the Arnot method deals with **bonding "repeat primers" onto the CS gene**. Indeed, this is clear from Figures 1 and 2 in Arnot which show the "binding sites" on the CS gene. In fact, nowhere does Arnot teach or suggest a "portion which is other than said gene portion" as in the claimed invention.

Further, in the claimed invention, the "nucleotide sequence" is "embedded in said

portion which is other than said gene portion". The Examiner alleges that this is disclosed by the "flanking primer" in Arnot being allegedly "embedded" in the "flanking region" in Arnot. **This is completely unreasonable.**

Indeed, the present Application states that in the claimed invention, a "nucleotide sequence" may be embedded in DNA "so that DNA including such a nucleotide sequence is distinguishable" (Application at page 11, lines 2-5). That is, the embedded nucleotide sequence may be referred to as a "watermark sequence". When the watermark sequence is embedded in DNA including a predetermined gene (e.g., a value-added gene), if the DNA including a value-added gene is copied during the breeding process, the source of the genetic information in the gene can be identified, and if the watermark sequence is detected in the DNA, it can be ascertained that the gene of the organism is a copy of the DNA wherein the watermark was previously embedded (Application at page 11, lines 9-21). (e.g., see Figures 8 and 9 of the present Application).

Thus, in light of the specification, Appellant again submits that the term "embedded" may be construed to mean "embedded" such that if the DNA including a value-added gene is copied during the breeding process, the source of the genetic information in the gene can be identified, and if the watermark sequence is detected in the DNA, it can be ascertained that the gene of the organism is a copy of the DNA wherein the watermark was previously embedded. Nowhere is this taught or suggested by Arnot.

Indeed, Appellant would again point out that the Examiner is surprisingly alleging that the "flanking primer" which is bound to a "flanking region" of the CS gene is "embedded". Appellant respectfully submits that this is clearly contrary to the use of the term "embedded" in the present Application and contrary to the use of the term "embedded" by one of ordinary skill in the art.

Appellant would again point out that the Examiner simply relies on a dictionary to construe the term "embedded" in claim 5, which is **directly contrary** to the decision in *Phillips v. AWH Corp.*, 415 F.3d.1301 (Fed. Cir. 2005) (en banc), in which the Federal Circuit concluded that intrinsic evidence, such as the claims, specification, and prosecution history, **is the most reliable evidence** by which a court can construe claim terms, whereas **extrinsic evidence, including dictionaries, is less reliable and should be used for limited**

purposes. The Court confirmed that extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, "can shed useful light on the relevant art," but noted that **such evidence is "less significant" than intrinsic evidence for construing claims**. Id. at *18 (emphasis added; quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Appellant again submits that the use of the term "embedded" in the present Application is clear and should be used to construe the terms of the claims. Clearly, therefore, Arnot does not teach or suggest a nucleotide sequence which is not naturally occurring in said DNA and **which is embedded in said portion which is other than said gene portion**, and comprises source identification information which identifies a source of said predetermined gene in said gene portion.

Further, the Examiner alleges that the flanking primer identifies a source of a predetermined gene (e.g., the CS gene). However, nowhere does Arnot teach or suggest that the flanking primer includes "source identification information". Indeed, the flanking primer is merely bound to the CS gene. The Examiner states that Arnot discloses the ability to trace malarial infection (Office Action at page 9). However, **nowhere does Arnot teach or suggest that a simple flanking primer (which is not "embedded" in DNA including the CS gene, by the way) which is bound to a CS gene can identify the source of the gene.**

Therefore, the Examiner's allegations are completely unreasonable.

Therefore, Appellant respectfully submits that Arnot clearly does not teach or suggest each and every feature of the claimed invention. Therefore, the Board is respectfully requested to withdraw this rejection.

VII. CONCLUSION

In view of the foregoing, Appellant submits that claims 5, 8-12, 15, 17-27 and 30-34, all the claims presently pending in the application, are patentably distinct from the prior art of record and in condition for allowance. Thus, the Board is respectfully requested to remove the rejections of claims 5, 8-12, 15, 17-27 and 30-34.

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Please charge any deficiencies and/or credit any overpayments necessary to enter this paper to Assignee's Deposit Account number 50-0510.

Respectfully submitted,

Dated: 12/18/06

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Reply Brief was filed by facsimile with the United States Patent and Trademark Office, Examiner Carolyn Smith, Group Art Unit # 1631 at fax number 571-273-8300 this 18th day of December, 2006.

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